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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/571,989	03/13/2006	Michael Kalafatis	CSU-17999	5552

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EXAMINER	
BARNHART, LORA ELIZABETH	
ART UNIT	PAPER NUMBER
1651	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/571,989	KALAFATIS, MICHAEL	
	Examiner	Art Unit	
	Lora E. Barnhart	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,10,43-49,51 and 112-135* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,10,43-49,51 and 112-135* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendments

Applicant's amendments filed 7/28/08 to claim 117 have been entered. No claims have been cancelled or added. Claims 1-8, 10, 43-49, 51, and 112-135 remain pending in the current application, all of which are being considered on their merits. Art references not included with this Office action can be found in a prior action. Any rejections of record not particularly addressed below are withdrawn in light of the claim amendments and applicant's comments.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 43-49, 51, 120-127, and 129-135 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 43, 120, and 128 are drawn to a composition "adapted for inhibiting thrombin formation," but it is not clear what physical properties of the composition render it particularly adapted for this function. Furthermore, the source of thrombin is not clear; the claim should point out from where or from what thrombin is formed. There is no antecedent basis for the term "thrombin formation" in the claims, because the compositions are drawn simply to compositions comprising peptides. The relationship between the peptide and some components that generate thrombin is not pointed out in the claim. Clarification is required. Because claims 44-49, 51, 121-127 and 129-135

depend variously from indefinite claims 43, 120, and 128 and do not clarify the point of confusion, they must also be rejected under 35 U.S.C. 112, second paragraph. Regarding this rejection, applicant alleges that the claims are definite (pages 12-13). These arguments have been fully considered, but they are not persuasive. The arguments appear to allege that the composition promotes the generation of thrombin when the composition comes in contact with a biological system that contains thrombin, but the claims are not so limited. It is noted that the only necessary component in each composition is a single peptide.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8, 10, 43, 44, and 51 remain rejected under 35 U.S.C. 102(b) as being anticipated by Hortin (1990, *Blood* 76: 946-952; reference AM on 3/13/06 IDS). The claims are interpreted as being drawn to a peptide comprising a sequence of amino acids that is identical to a sequence of at least 2 consecutive amino acids found within a 4-amino acid region of a longer reference sequence. In some dependent claims, the peptide has a particular activity or comprises a particular sequence. Some claims are drawn to compositions comprising the peptide or compounds that mimic the peptide in some way. It is noted for the record that claim 1 is currently so broad as to encompass any peptide that contains either the sequence DY or the sequence YD along with any

other amino acids in any sequence. The scope of claim 43 encompasses any peptide that contains the sequence DYDY along with any other amino acids in any sequence.

Hortin teaches that the complete sequence of human coagulation factor V (hereafter "Factor V") was known at the time of the invention and that said sequence includes the sequence DYDYQ (page 946, column 1, paragraph 2; and Figure 6 at page 950, e.g.). Hortin teaches a solution comprising Factor V (page 946, column 2, last paragraph).

M.P.E.P. § 2112 recites, "Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established." *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433. See also *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985). In this case, the claims encompass numerous peptides, including Factor V itself. Peptides cannot be separated from their inherent properties, and since the peptide as instantly claimed is identical in structure to the prior art peptide, the two necessarily have the same properties,

including those recited in claims 2-5 and 43. Claims 10 and 51 are included in this rejection because a given composition is a perfect mimic of itself in every way.

Applicant alleges that the length of the peptide in the claimed composition is limited by the definitions known in the art (Reply, pages 15-17). Applicant alleges that Hortin does not teach the peptides DYDY or DYDYQ (Reply, page 18). Applicant alleges that Hortin does not teach a pharmaceutical composition (Reply, page 18). Applicant alleges that Hortin does not teach the properties of the peptides encompassed by the claims (Reply, page 19). These arguments have been fully considered, but they are not persuasive.

Applicant's allegation regarding the definitions of "peptide" and "protein" are wholly unsubstantiated by evidence, e.g. dictionary definitions or declarations of those skilled in the art. The Merriam-Webster Online Medical Dictionary (see reference U) makes no distinction between the length of a peptide and the length of a protein. Indeed, various patents issued around the time of the instant filing also fail to make such distinctions (see Sukhatame, U.S. Patent 6,673,341, reference A, at column 9, lines 23-25: "'Polypeptide' as used herein… does not refer to a specific length of the product."; Sun et al., U.S. Patent Application Publication 2004/0005688, reference B, at paragraph 36). The art appears to consider the terms "peptide" and "protein" as synonyms of each other (and of the term "polypeptide"). Applicant has provided no evidence in support of his position; even if a definition supporting applicant's position were provided, such submission would merely establish that the terms' definitions were

in dispute in the art. If the length of the peptide in the instantly claimed compositions is an essential aspect of the invention, the claims should be so limited.

Applicant alleges that Hortin does not teach the tetrapeptide DYDY or the pentapeptide DYDYQ; this point is not in dispute. None of the cited claims limits the sequence or length of the protein except claims 6, 7, and 43, which only require that the peptide include a few particular residues in a row. Claim 112, for example, which limits the length and sequence of the peptide to the tetrapeptide DYDY, is not included in this rejection.

Regarding the teaching of a pharmaceutical composition that comprises the peptides of the claims, Hortin teaches Factor Va in a physiological buffer containing HEPES and salt (page 946, column 2). The buffer of Hortin does not contain any components that would preclude its being administered to a patient. If the composition of claim 43 necessarily includes some particular component, the claim should reflect the same.

To invalidate a patent by anticipation, a prior art reference normally needs to disclose each and every limitation of the claim. See *Standard Havens Prods., Inc. v. Gencor Indus., Inc.*, 953 F.2d 1360, 1369, 21 USPQ2d 1321, 1328 (Fed. Cir. 1991). However, a prior art reference may anticipate when the claim limitation or limitations not expressly found in that reference are nonetheless inherent in it. See *id.* and *Verdegaal Bros., Inc. v. Union Oil Co. of Cal.*, 814 F.2d 628, 630, 2 USPQ2d 1051,1053 (Fed. Cir. 1987). Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates. See *In re King*, 801

F.2d 1324, 1326, 231 USPQ 136, 138 (Fed. Cir. 1986). **Inherency is not necessarily coterminous with the knowledge of those of ordinary skill in the art.** See *Titanium Metals*, 778 F.2d at 780. Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art. See *id.* at 782. However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. See *id.* at 782 ("Congress has not seen fit to permit the patenting of an old [composition], known to others…, by one who has discovered its…useful properties."); *Verdegaal Bros.*, 814 F.2d at 633.

This court's decision in *Titanium Metals* illustrates these principles. See *Titanium Metals*, 778 F.2d at 775. In *Titanium Metals*, the patent applicants sought a patent for a titanium alloy containing various ranges of nickel, molybdenum, iron, and titanium. The claims also required that the alloy be "characterized by good corrosion resistance in hot brine environments." *Titanium Metals*, 778 F.2d at 776. A prior art reference disclosed a titanium alloy falling within the claimed ranges, but did not disclose any corrosion-resistant properties. This court affirmed a decision of the PTO Board of Appeals finding the claimed invention unpatentable as anticipated. This court concluded that the claimed alloy was not novel, noting, "it is immaterial, on the issue of their novelty, what inherent properties the alloys have or whether these applicants discovered certain inherent properties." *Id*. at 782. This same reasoning holds true when it is not a property, but an ingredient, which is inherently contained in the prior art. The public remains free to make, use, or sell prior art compositions or processes,

regardless of whether or not they understand their complete makeup or the underlying scientific principles which allow them to operate. The doctrine of anticipation by inherency, among other doctrines, enforces that basic principle." See *Atlas Powder Co. v. IRECO Inc.*, 51 USPQ2d 1943 (Fed. Cir. 1999).

Thus, a reference may be anticipatory if it discloses every limitation of the claimed invention either explicitly or inherently. A reference includes an inherent characteristic if that characteristic is the natural result flowing from the reference's explicitly explicated limitations. *Continental Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 1269, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991).

In the instant case, the properties of claims 2-5 flow from the fact that the peptide instantly claimed is identical to that taught by Hortin. Thus applicants are incorrect in arguing that the anticipatory rejection is improper. It is also noted that claims 2-5 define the activity of the peptide in terms of their activity against "human factor Va," but the claims do not limit the factor Va to any particular variant of human factor Va. Mutant Factor Va alleles with varying degrees of activity exist in nature and lead to clotting disorders and thrombosis. Therefore, claims 2-5 do not effectively limit the claims as applicant alleges.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 6-8, 10, 43-49, 51, and 112-135 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hortin (1990, *Blood* 76: 946-952; reference AM on 3/13/06 IDS) taken in view of Pittman et al. (1994, *Biochemistry* 33: 6952-6959; reference AO on 3/13/06 IDS), Bakker et al. (1994, *Journal of Biological Chemistry* 269: 20662-20667; reference U), and Ramabhadran (1994, *Pharmaceutical Design and* Development, Ellis Horwood, New York NY, pages 40, 42, and 43; reference V).

Hortin teaches that the complete sequence of human coagulation factor V (hereafter "Factor V") was known at the time of the invention and that said sequence includes the sequence DYDYQ (page 946, column 1, paragraph 2; and Figure 6 at page 950, e.g.). Hortin teaches that Factor V is sulfated *in vivo* suggests that the tyrosine residues at positions 696 and 698 are among the residues that are sulfated (page 950, column 2). Hortin speculates that thrombin binding to Factor V may be mediated by binding to these sites (page 951, column 1). Hortin teaches a solution comprising Factor V (page 946, column 2, last paragraph).

Hortin does not exemplify a peptide in which one or both of the tyrosines in the DYDY or DYDYQ motif are sulfated. Hortin does not teach any fragments of Factor V, e.g. the tetrapeptide DYDY or the pentapeptide DYDYQ.

Pittman teaches that inhibiting sulfation of Factor V inhibits its procoagulant activity (page 6955, column 1, under "Sulfation is required..."). Specifically, Pittman teaches that Factor V must be sulfated to undergo binding and subsequent cleavage by thrombin (page 6956, column 1; and Figure 3B). Pittman concurs with Hortin that tyrosines 696 and 698 are likely candidates for the sulfation (page 6957, column 1, under “Discussion”). Pittman also teaches methods for sulfating proteins (pages 6953 and 6954).

Bakker teaches that the portion of Factor V heavy chain required to bind thrombin is the C-terminal 27 amino acids thereof, which comprises the DYDYQ motif (see Table II at page 20665 and page 20664, column 1, first full paragraph). Bakker further teaches that these 27 amino acids are responsible for the binding of Factor V to prothrombin (page 20667, column 1, first full paragraph).

Ramabhadran teaches that small peptides (i.e., up to 50 amino acids) may be made in high yield and with high purity by synthesizing them chemically from their constituent amino acids (page 43). Ramabhadran teaches that chemically synthesized peptides are useful in the laboratory as drugs (page 43, third full paragraph).

A person of ordinary skill in the art would have had a reasonable expectation of success in sulfating either or both of the tyrosine residues at positions 696 and 698 within Factor V because Hortin and Pittman both teach that these residues are within

consensus sequences for sulfation. The skilled artisan would have been motivated to sulfate one or both of these residues in Factor V because Pittman teaches that Factor V is not active unless it is sulfated.

The person of ordinary skill in the art would have had a further reasonable expectation of success in producing short peptides including tyrosine residues 696 and 698 because Hortin teaches that the entire sequence of Factor V was known at the time of the invention and because Ramabhadran teaches that peptides of up to 50 amino acids in length and with a given sequence may be chemically synthesized. The skilled artisan would have been motivated to produce such peptides because Bakker teaches that the C-terminal portion of Factor V heavy chain, which comprises tyrosine residues 696 and 698, is the domain required to bind prothrombin; the skilled artisan would have been motivated to determine which of these 27 residues is necessary for the interaction and which are not. Furthermore, sulfating these residues would have constituted routine experimentation on the part of the skilled artisan, since Pittman teaches methods for doing so. The skilled artisan would have been motivated to sulfate the tyrosine residues because Pittman and Horton both teach that they may be sulfated *in vivo*, because Bakker teaches that these residues are within a domain that binds prothrombin, and because Pittman teaches that Factor V must be sulfated to bind thrombin. Therefore, the skilled artisan would have endeavored to learn whether the tyrosine residues in the 27-amino acid peptide of Bakker need be sulfated to bind prothrombin. In light of the practical teachings and predictions of the art, the selection of the peptide sequence and

sulfation pattern would have constituted routine experimentation at the time of the invention. See *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007).

The skilled artisan would have had a reasonable expectation that peptides made as suggested by the art as set forth above would inhibit thrombin activity because Hortin teaches that Factor V is bound and cleaved by thrombin, Bakker teaches that the C-terminal 27 amino acids of Factor V are the portion involved in binding thrombin, and Pittman and Horton teach that residues 696 and 698 are likely required for thrombin binding. See *KSR*.

It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was made to produce peptides using the method of Ramabhadran that correspond to various portions of the 27 amino acids of Factor V taught by Bakker to be involved in binding thrombin in order to determine which portions of this fragment are necessary for thrombin binding. It would have been further obvious to sulfate one or more of the tyrosine residues within the resulting peptide because Pittman teaches that sulfation is required for activity and teaches methods for sulfating proteins.

Therefore, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill at the time the invention was made.

Applicant alleges that the examiner engaged in improper hindsight reasoning in constructing the rejection (Reply, pages 22-23). Applicant alleges that Figures 10-13 include evidence of unexpected results (Reply, page 24). Applicant alleges that Bakker teaches away from the claimed invention (Reply, pages 24-25). These arguments have been fully considered, but they are not persuasive.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In this case, Hortin teaches that Factor V is bound and cleaved by thrombin, Bakker teaches that the C-terminal 27 amino acids of Factor V are the portion involved in binding thrombin, Pittman and Horton teach that residues 696 and 698 are likely required for thrombin binding, and Ramabhadran teaches methods for producing small peptides of a given sequence. Taken together as set forth in the rejection, the cited art identifies that C-terminal portion of Factor V as involved in thrombin binding and that two particular residues in that portion are particularly important. Identifying peptides from the C-terminal 27 amino acids that include those two residues (696 and 698) would have been obvious at the time of the invention, given the teachings of the art taken together.

Figures 10-13 have been considered, but it is submitted that these figures only provide information about a few embodiments within the broader claims. Furthermore, applicant's reply does not clearly indicate what aspects of this data are unexpected; rather, the reply refers to the figures generally. The burden is on applicant to explain

data, particularly pointing out that it represents results that are both unexpected and significant. See M.P.E.P. § 716.02(b).

It is respectfully submitted that applicant has misinterpreted the teachings of Bakker. The Va_{NO} of Bakker that is discussed in the passage referenced by applicant (page 20665 of Bakker and page 24 of the reply) is not a peptide that consists of the last 27 amino acids of Factor Va, but rather a peptide that includes the entire sequence of Factor Va except for these last 27 amino acids. "[T]he heavy chain of factor Va_{NO} had a slightly increased electrophoretic mobility, indicating the loss of a small peptide … from the heavy chain" (page 20663, column 2, third full paragraph). Bakker teaches that when the C-terminal 27 amino acids are removed from Factor Va, the resulting peptide (Va_{NO}) activates thrombin more effectively than does native Factor Va; the reply appears to stipulate to the fact that Va_{NO} is a less effective thrombin inhibitor than is Factor Va. The skilled artisan would have concluded from these teachings that these C-terminal 27 amino acids possess an activity that inhibits thrombin activation. This C-terminal portion would therefore have been a region of interest to artisans seeking thrombin inhibitors.

No claims are allowed. No claims are free of the art.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lora E. Barnhart whose telephone number is (571)272-1928. The examiner can normally be reached on Monday-Thursday, 9:00am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lora E Barnhart/
Primary Examiner, Art Unit 1651